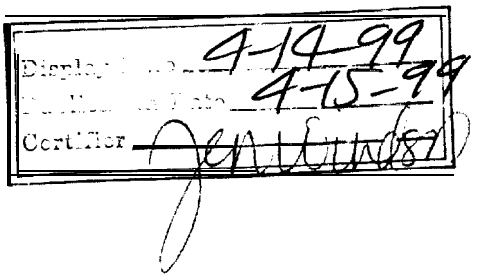
DMB



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Omeprazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merial Ltd. The NADA provides for oral use of omeprazole for the treatment and prevention of recurrence of gastric ulcers in horses and foals 4 weeks of age and older.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827–7543.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ron son Rd., Iselin, NJ 08830-3077, filed NADA 141-123 that provides for oral, veterinary prescription use of GastroGard® (omeprazole) oral paste for horses and foals 4 weeks of age and older for the treatment and prevention of recurrence of gastric ulcers. The NADA is approved as of March 16, 1999, and the regulations are amended by adding 21 CFR **520.1615** to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.110, a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food

cv9914 NADA 141-123 NFR "/

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512 of the Federal, Food, Drug and Cosmetic Act (the act) (21U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning March 16, 1999, because no active ingredient (including any ester or salt thereof) has been previously approved in any other application filed under section 5 12(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1615 is added to read as follows:

§ 520.1615 Omeprazole.

(a) *Specifications.* Each **gram** of oral paste contains 0.37 gram of omeprazole.

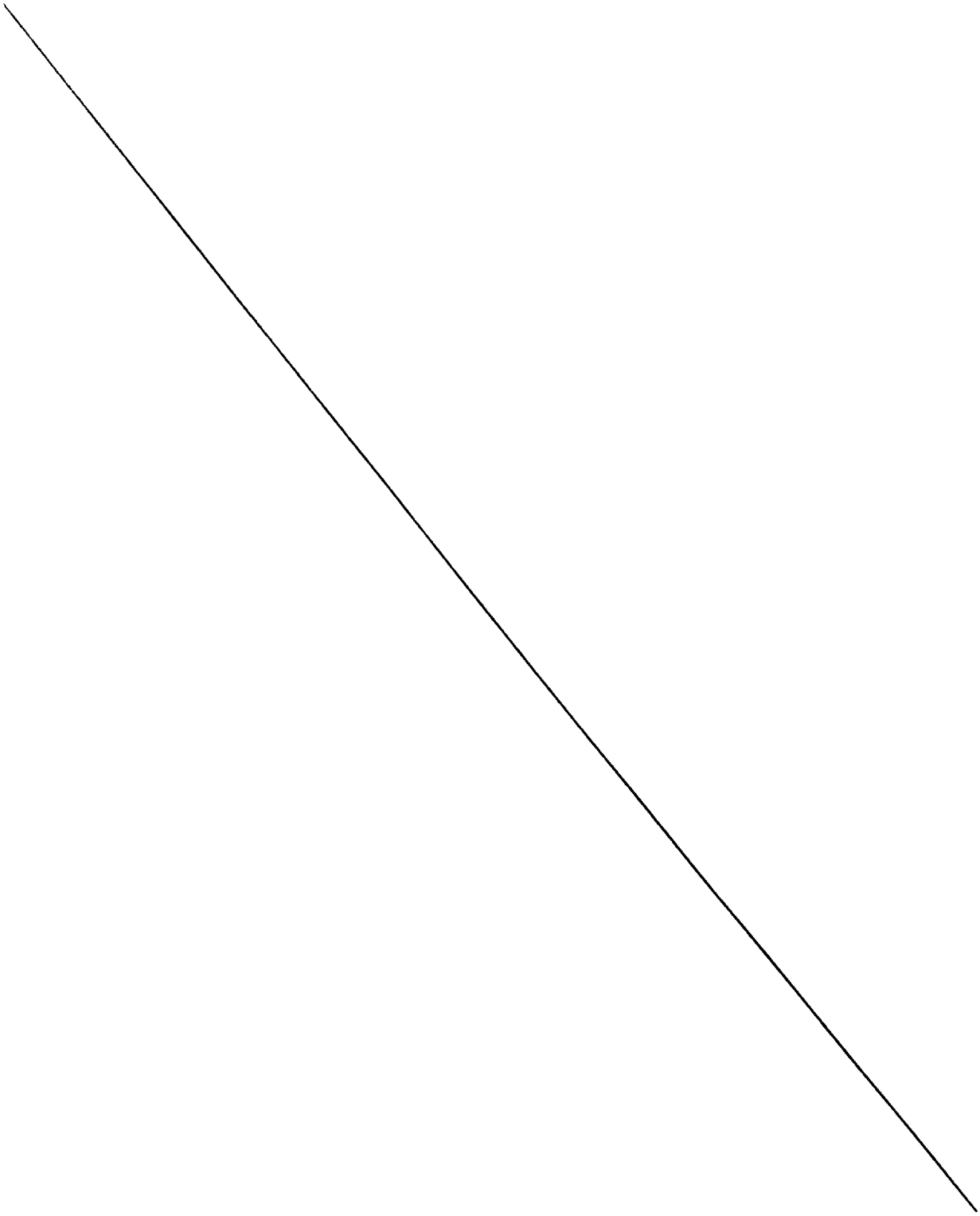
(b) *Sponsor. See No. 050604* in § 51O.6OO(C) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* For treatment of gastric ulcers, 1.8 milligrams of omeprazole per pound of body weight (4 milligrams per kilogram) once daily for 4 weeks. For

prevention of recurrence of gastric ulcers, 0.9 milligram of omeprazole per pound of body weight (2 milligrams per kilogram) once daily for at least an additional 4 weeks.

(2) Indications *for use.* For treatment and prevention of recurrence of gastric ulcers in horses



and foals 4 weeks of age and older.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 4/1/99

April 1, 1999

George A. Mitchell
Acting Director
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

[FR Dec. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F